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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,037	01/22/2004	Robert J. Schwartz	HO-P02659US1	8488
26271 7590 01/16/2009 FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095				
EXAMINER				
LONG, SCOTT				
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
01/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/763,037

**Applicant(s)**

SCHWARTZ ET AL.

**Examiner**

SCOTT LONG

**Art Unit**

1633

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 07 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 5,6 and 8-15.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633

Continuation of 11, does NOT place the application in condition for allowance because: The applicant makes numerous arguments in traverse of the examiner's rejection of the instant claims based on unpatentability under 35 USC 103 over Drewett in view of Narula.

The applicant argues the case law with respect to unpredictable arts (Remarks, pages 4-7). Not being a lawyer, the examiner feels he cannot professionally argue the nuances of the Court's decisions. The examiner has attempted in the prior actions to make a prima facie case, based upon the science presented by the cited art and the examiner's rudimentary understanding of how to apply the specific laws for which the examiner has had some training (i.e., 35 USC 103(a)). According to the examiner's reading of Applicant's remarks, pages 4-7, the applicant seems to be making something like a lack of enablement argument in traverse of the examiner's obviousness rejection. Despite all the insightful critiques and suggestions of unpredictability raised by the applicant, the examiner finds that the cited art teaches or suggests the limitations of the instant claims. Accordingly, the examiner finds this argument unpersuasive.

The applicant further argues (Inventive Concepts of the Present Application section, page 7), "that there is at least one non-obvious concept disclosed for the first time in the current application, That is, that SRF cleavage is useful in diagnosing cardiac disease." Contrary to the applicant's assertion, the examiner finds one of ordinary skill in the art would have concluded the cited art indicate a link between SRF cleavage and cardiac disease. Narula et al. indicate a link between apoptosis and heart failure, while Drewett et al., describe the relationship between Serum Response Factor (SRF) cleavage and apoptosis. In particular, Drewett teach SRF cleavage by caspases 3 and 7 is linked to apoptosis and also teaches measurement of the N-terminal region of SRF (which comprises SEQ ID NO:5). Drewett indicates that this cleavage occurs in both fibroblasts and the B-cell line, BJAB. Furthermore, Drewett indicate that both caspase 3 and 7 cleavage sites are conserved from zebrafish to humans (page 33450, col.1, last few lines), suggesting that their conclusions are applicable to numerous cell types in vertebrates. The applicant suggests "there was no reason to select this particular gene and this particular cleavage site as an indicator out of thousands of possibilities" (Remarks, page 7, lines 24-26). The prior art seems to suggest otherwise. Therefore, the examiner finds the applicant's argument unpersuasive.

The applicant discusses the differences between the cited art and the instant claims (Remarks, pages 8-9). In particular, the applicant suggests "that all types of cells cannot be expected to respond in the same manner to stimuli [as the BJAB cells used by Drewett]." Contrary to the applicant's assertion, the examiner finds that the teachings of Drewett suggest that many cell types respond in the same manner. Drewett indicates that cleavage occurs in both fibroblasts and the B-cell line, BJAB. Furthermore, Drewett indicate that both caspase 3 and 7 cleavage sites are conserved from zebrafish to humans (page 33450, col.1, last few lines), suggesting that their conclusions are applicable to numerous cell types in vertebrates. The teachings of Drewett seems to suggest that caspase cleavage of many different cells is similar and is predictable. Therefore, the examiner finds the applicant's argument unpersuasive.

The applicant further argues that Narula does not provide direct evidence that specific types of SRF cleavage also occur in hearts (Remarks, page 8, para.4). The applicant is correct, Narula is not a 102-type reference. However, Narula in conjunction with Drewett supports the examiner's conclusion of obviousness. Narula teach caspase-3 cleaves cytoplasmic and nuclear substrates for manifestation of apoptosis (page 8147, col.1). Narula also teach apoptosis has been shown to contribute to loss of cardiomyocytes in cardiomyopathy and heart failure and is a predictor of adverse outcomes in patients with congestive heart failure (page 8144). Together with all the previous actions, the examiner believes he has provided sufficient support for the prima facie case of obviousness over the instant claims, given the current breadth of the instant claims.

Accordingly, the pending claims remain rejected for the reasons of record and the comments above.

At present, SEQ ID NO:5 is merely identified as a region of SRF N-terminus and was rejected as being obvious over methods comprising detecting the SRF N-terminus. If the applicant believes this fragment is somehow novel and not merely random epitope of the N-terminus of SRF, the examiner suggests that if the applicant wishes to continue prosecution, that the applicant draft claim language which highlights the importance of this unique feature.

/SD/ Scott Long, patent examiner, art unit 1633.

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